

REMARKS

The Examiner has rejected claims 18-23 under 35 U.S.C. § 102(a) and 102(e) as being anticipated by Schork et al. (U.S. Patent No. 6,291,182; hereinafter the '182 patent). Applicants respectfully traverse the Examiner's rejection. The '182 patent does not anticipate claim 18, or its dependent claims 19-23.

Anticipation exists only if all the elements of the claimed invention are present in a product or process disclosed, expressly or inherently, in a single prior art reference. *Hazeltine Corp. v. RCA Corp.*, 468 U.S. 1228 (1984). Claim 18 of the above-captioned application specifies "a fluorimeter for detecting fluorescence during amplification of the nucleic acid." The '182 patent does not describe "a fluorimeter for detecting fluorescence during amplification of the nucleic acid" as required by claim 18. Furthermore, claim 18 has been amended to add the phrase "wherein the scores are generated during nucleic acid amplification and wherein the scores are used, during nucleic acid amplification, to ascertain whether the nucleic acid is present in the sample" to clarify that the processor analyzes data during amplification of the nucleic acids. The '182 patent does not describe a processor that analyzes data during amplification of nucleic acids to ascertain whether the nucleic acid is present in the sample.

The Examiner indicates that the '182 patent discloses a fluorimeter and Picogreen to determine quantities of amplification products and refers to column 47, lines 7-9 of the '182 patent (Example 6). However, although Example 6 discloses a fluorimeter and the use of Picogreen to quantitate nucleic acids, the fluorimeter and Picogreen are used to determine quantities of amplification products after amplification is complete in samples from the amplification reaction after final elongation that are aliquoted into 96-well plates. Thus, the quantities of amplification products are determined after the amplification reaction is complete (see column 47, lines 1-9).

The Examiner also refers to the sequencing method described in Example 6 and indicates that the '182 patent discloses the use of dideoxy terminator sequencing reactions to determine sequences of amplification products wherein the sequence data is evaluated using software designed to detect sites among the amplified products via different fluorescent molecules and by evaluating intensity ratios. The Examiner refers to column 47, lines 10-15 and column 47, lines 10-28 in Example 6 of the '182 patent. However, the sequencing reactions described in Example 6 of the '182 patent are done using dideoxy terminators, each labeled with a different fluorescent molecule, and the sequences are analyzed by running the products of the sequencing reaction on sequencing gels and then using gel image analysis of the sequencing gels to determine the sequences (see column 47, lines 11-36). The fluorescence measurement in this sequencing protocol is the gel image analysis that is used to determine the sequence. The sequence data from the gel image analysis is then evaluated using software designed to detect the presence of a nucleic acid in a sample. Thus, the fluorescence measurement that is related to the sequencing protocol described in Example 6 is done after amplification of the nucleic acid. In other words, the gel image analysis (*i.e.*, the fluorescence measurement) is done on samples run on a sequencing gel and the samples are run on the sequencing gel after amplification is complete.

Accordingly, for the devices and methods described in the '182 patent, the fluorescence measurements are done after the amplification of the nucleic acids is complete and the analysis of the data generated from the fluorescence measurements is done after amplification of the nucleic acids is complete. No where does the '182 patent describe a fluorimeter for detecting fluorescence during amplification of the nucleic acid or a processor that analyzes data during amplification of nucleic acids. Thus, the '182 patent does not describe all of the required elements of claims 18-23 and the '182 patent cannot anticipate

claims 18-23. Withdrawal of the rejection of claims 18-23 under 35 U.S.C. § 102(a) and 102(e) is respectfully requested.

CONCLUSION

The foregoing amendments and remarks are believed to fully respond to the Examiner's rejection. The amended claims are in condition for allowance. Applicants respectfully request allowance of the claims, and passage of the application to issuance.

Respectfully submitted,

A handwritten signature in black ink that reads "Rebecca Ball". The signature is written in a cursive, flowing style.

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